**Iain Pulley**

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## PROFESSIONAL SYNOPSIS

A dynamic professional with around 13 **years** of experience in **Quality Assurance and GCP Auditing**. I am an independent **Good Clinical Practice (GCP) Auditor** and **Managing Director of Closed Loop Quality Ltd**, **presently** collaborating with **M/S GXPZONE Pharma Solutions Pvt. Ltd**. With a **BSc (Hons) in Product Design**, I am passionately process-orientated, and place **strong emphasis** on ensuring quality management systems add value to achieve right-first-time results. I have excellent communication & interpersonal skills, with strong analytical, team building, problem solving and organizational abilities. I also have an **Associate** qualification in **project management** from the **Association for Project Management (APM)**.

I have successfully participated in 6 inspections by regulatory authorities such as the **Medicines and Healthcare products Regulatory Agency (MHRA)** and **UK Prescription Medicines Code of Practice Authority (PMCPA)**, and have also successfully performed three inspections in the role of a **mock inspector**.

I have a wide experience in conducting and overseeing **Global GCP audits**, and have executed more than **140 investigational site, vendor, system/process and for-cause audits** across **Europe**, the **United States**, as well as **parts of Asia, Africa and South America**.

## CORE COMPETENCIES

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| **Quality Assurance / Auditing** | ❖ Analysis and interrogation of systems/processes to identify the key inputs and outputs to demonstrate their correct performance.<br>❖ Collaboration and communication with interviewees to correctly understand procedures and their execution.<br>❖ Analyse audit results in accordance with client requirements and relevant guidelines, diagnose quality critical issues, assess Corrective and Preventive Actions (CAPA) to achieve successful audit closure.<br>❖ Risk assessment of suppliers and processes from a quality perspective, and to ensure delivery of a regulatory compliant audit program.<br>❖ Provide executive summaries and key areas of risk that could impact the quality, safety and efficacy of clinical trials within the audit scope.<br>❖ Audit report writing, peer review, and clear communication of audit observations within the audit report. |

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| | ❖ Planning, execution and oversight of internal and outsourced quality audits, and escalation to senior management of significant observation and/or clinical trial risks.<br>❖ GCP auditing and pharmaceutical Quality Management Systems (QMS).<br>❖ Conducting investigational site, vendor, system/process and for-cause audits.<br>❖ Investigation, root cause analysis and CAPA.<br>❖ Expertise in implementation of ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) principles.<br>❖ Reduction of deviations due to human error, and identification of opportunities for adding-value to QMS activities. |
| **Work Experience** | |
| Designation: **Director / GCP Auditor**<br>**Closed Loop Quality Ltd.** **May 2019 - Present** | |
| Job Profile: | **Day-to-day Responsibilities:**<br>❖ Development of business strategies, client networks, and opportunities for collaboration and service provision.<br>❖ Performance of international GCP investigational site, system / process, vendor and for-cause audits for client organisations.<br>❖ Provision and performance of mock inspection and inspection facilitation support services.<br>❖ Continuous development of a network of independent quality assurance professionals across multiple GxP disciplines.<br>❖ Identification and transformation of GxP audit opportunities to leverage the above network.<br>**Core Responsibilities:**<br>❖ Support the audit and quality assurance programs of client organisations.<br>❖ Share industry best-practice and experiences. |
| Designation: **GCP Auditor, Quality Medicine**<br>**Boehringer Ingelheim** **Jun 2012 to Apr 2019** | |
| Job Profile: | **Day-to-day Responsibilities:**<br>❖ Responsible for all activities within QM for specific countries/regions to ensure robust audit plans and inspection preparedness, thereby ensuring that BI met both its business needs and up-held regulatory compliance.<br>❖ Ensure early identification and escalation of quality initiatives to support research activities.<br>❖ Active member of QM through performing site, system, process and vendor audits. |

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| | **Core Responsibilities:**<br>❖ Identified areas of risk in liaison with other functions, and developed appropriate audit programs.<br>❖ Supported the inspection program in the UK and other countries, as required.<br>❖ Supported the QM compliance and training functions.<br>**Achievements:**<br>❖ Re-vamping of QM Auditing plan and report templates, mapping and harmonisation of 20+ specific audit types into four all-purpose audit categories.<br>❖ Mock PMCPA audit coaching and execution for BI Healthcare against the UK Code of Compliance.<br>❖ Successful oversight and execution of BI Biosimilars and fully-outsourced trial audit programs.<br>❖ Successful execution of Mock MHRA inspection in the BI UK office. |
| Designation: **Auditor, Global Research & Development Quality Assurance**<br>**Allergan Ltd.** **Dec 2009 to Jun 2012** | |
| Job Profile: | **Day-to-day Responsibilities:**<br>❖ Responsible for the implementation/execution of quality assurance/authorship for GCP and general compliance processes to ensure trial compliance.<br>❖ Participated and led internal/external audits of studies, validation systems, facilities, vendors and investigator sites.<br>❖ Provided internal consultancy to the organisation and study teams on quality / regulatory related issues for operational groups, and advised on the implementation of corrective / preventative actions.<br>**Core Responsibilities:**<br>❖ Co-ordination of preparation activities for regulatory agency inspections (Both internal mock and external), and resolved any compliance observations.<br>❖ Writing, review and revision of GRDQA SOPs.<br>❖ Participation both as a team member and independently to perform study audits, review observations/responses and perform follow-up activities as necessary.<br>❖ Independently identified audit trends and system problems.<br>**Achievements:**<br>❖ Successful completion as audit lead of audit programs for overactive bladder, benign prostatic hyperplasia and crow's feet.<br>❖ Successful execution of logistics for the 2012 MHRA pharmacovigilance inspection. |

**Other Positions:**

- **Clinical Quality Assurance Auditor I, Kendle International (Apr 2007 – Nov 2009)**
- **Project Assistant, Kendle International (Mar 2005 – Apr 2007)**
- **Senior Records Specialist / Mentor, PRA International (Jan 2002 – Mar 2005)**

## AUDIT EXPERIENCE

| Sr. No. | Type of Facility | No. of Audits |
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| 1. | Investigator Site Audits (Including 6 for-cause audits) | **93** |
| 2. | System / Process Audits | **31** |
| 3. | Vendor Audits | **22** |

## PERSONAL TRAITS

- Analysis and problem solving.
- Proficient in delivering timely and productive results in tight deadlines without compromising quality.
- Strong work-ethic, discipline and self-motivated.
- Good Interpersonal and communication skills.
- Highly-motivated and tenacious.
- Self-confident, calm, and composed.